K080169

11.0 510(K) SUMMARY

FEB - 8

Submitter	Guidant Corporation, Cardiac Surgery
Submitter's Address	170 Baytech Drive San Jose, CA 95134
Telephone	(408) 635-6835
Fax	(408) 635-3907
Contact Person	Elizabeth Trujillo
Date Prepared	December 10, 2007
Device Trade Name	HEARTSTRING® III Proximal Seal System
Device Common Name	Proximal Seal System
Device Classification Name	Vascular Clamp
Device Classification	Class II
Summary of substantial equivalence	The design, materials, method of delivery, and intended use features of the HEARTSTRING® III Proximal Seal System are substantially equivalent with regard to those features in the predicate devices: the HEARTSRING II and the HEARTSTRING (K022880, September 13, 2002).
Device description	The HEARTSTRING® III Proximal Seal System delivers a hemostatic seal device designed to enable the proximal anastomosis of an aortic graft without the need for an aortic clamp during coronary artery bypass graft (CABG) surgery. The Proximal Seal System is comprised of the Proximal Seal, Delivery Device, Loader and the Aortic Cutter. The proximal Seal is a semi-spherical shaped device that is delivered into the aorta via the punch hole site and provides a sealed region to facilitate the proximal anastomosis. The Loader is a mechanism that rolls the Proximal Seal and loads the Seal into the Delivery Device. The Delivery Device is a plastic injected molded device that is used to deploy the Seal inside of the aorta. The HEARTSTRING® Aortic Cutter creates the aortotomy and hole opening in the aorta for the anastomosis.
Indications for Use	The Proximal Seal System is intended for use by cardiac surgeons during CABG procedures to maintain hemostasis and to facilitate the completion of a proximal anastomosis without application of an aortic clamp.
Technological characteristics	The Guidant HEARTSTRING® III Proximal Seal System incorporates the same fundamental scientific technology as the predicate devices.
Performance data	The results of the verification testing demonstrate that the Guidant HEARTSTRING® III Proximal Seal System meet the established acceptance criteria and performs in a manner equivalent to the predicate devices. No new safety or effectiveness issues were raised during the testing program.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2008

Guidant Corporation
c/o Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
Northbrook, IL 60062-2096

Re: K080169
HEARTSTRING® III Proximal Seal System
Regulation Number: 21 CFR §870.4450
Regulation Name: Vascular clamp
Regulatory Class: II
Product Code: DXC
Dated: January 15, 2008
Received: January 24, 2008

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

12.0 INDICATIONS FOR USE STATEMENT

510(k) number (if known)	The 510(k) number has not been issued yet. K080169
Device name	HEARTSTRING® III Proximal Seal System
Indications for Use	The Proximal Seal System is intended for use by cardiac surgeons during CABG procedures to maintain hemostasis and to facilitate the completion of a proximal anastomosis without application of an aortic clamp.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Donna R. Mc Nally
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080169